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Response to Office Action of 5 December 2005

Atty Docket 200512.00036

**REMARKS/ARGUMENTS****Election of Inventions**

The Examiner has required an election of a single invention for prosecution on the merits. The Examiner has identified the following inventions:

- I Claims 1-19 drawn to a method of inhibiting HIV entry into a cell or HIV infection and the contraction of HIV in a subject, comprising contacting the cell with an effective amount of an agent or administering to the subject an effective amount of an agent, classified in class 424, subclass 185.1;
- II Claims 1, 2, and 20-24, drawn to a method of inhibiting HIV infection and the contraction of HIV in a subject, comprising administering to the subject an effective amount of an agent in combination with an additional antiviral agent, classified in class 424, subclass 9.2;
- III Claims 25-39, drawn to a method of identifying a BD-inducing agent, classified in class 435, subclass 7.1;
- IV Claims 35-39 drawn to a method of identifying agents that potentiate the interaction between a BD-polypeptide and receptor classified in class 435, subclass 7.1.

The Applicant elects the claims of Group I, claims 1-19, with traverse. The Examiner's position is that the inventions are distinct because they have different modes of operation, with respect to starting materials physiological mechanisms, protocol procedures and end products.

As a preliminary matter, it should be noted that claims 1 and 2 have been classified into both Groups I and II, which the Examiner also maintains are distinct. The Examiner also mischaracterizes claims 1 and 2 in describing them as "drawn to a method of inhibiting HIV infection and the contraction of HIV in a subject, comprising administering to the subject an effective amount of an agent in combination with an additional antiviral agent." No additional antiviral agent is recited in claims 1 and 2. Furthermore, claims

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20-24 depend, either directly or indirectly, from claims 1-3 and incorporate all the limitations of claims 1-3. Therefore, the Examiner has not established that these claims are distinct or independent.

The Applicant further traverses the restriction requirement on the basis that the Examiner has misclassified the claims of Groups I and II. The claims of Group I have been classified in class 424, subclass 185.1, while the claims of Group II have been classified in class 424, subclass 9.2. Subclass 185.1 includes, "Subject matter wherein an amino acid sequence specifying an antigen, an epitope or another immunoeffector is disclosed in whole or in part wherein the disclosed amino acid sequence may be part of a conjugate, a complex, or a fusion protein or fusion polypeptide." However, subclass 9.2, includes "subject matter wherein the capacity of a compound or composition (e.g., drug, vaccine, etc.) to produce a desired effect or an injurious or harmful effect in a living subject is tested for." None of claims 1, 2, and 20-24 recite such subject matter. Therefore, the Applicant maintains that the Examiner has misclassified at least some of the claims subject to the restriction requirement and that therefore, the restriction requirement is improper.

The Examiner further required election of one amino acid sequence SEQ. ID. NO. and one encoding nucleic acid sequence SEQ. ID. NO. on the basis that the inventions reflected in these sequences are not related as capable of use together and have different modes of operation, different functions or different effects. The Examiner maintains that the different sequences represent structurally different polypeptides and the nucleotides encoding them. However, the sequences disclosed are not each structurally different from each of the other sequences. SEQ. ID. NOs. 1 and 2 are each a Beta-defensin agent polypeptide, specifically, human Beta-defensin 2 agent. Examination of SEQ. ID. NOs. 4-7 reveals these to be nucleic acid sequences encoding human Beta-defensin 2 agents. SEQ. ID. NOs. 4-7 vary only in so far as they encode the gene (SEQ. ID. NO. 4), mRNA (SEQ. ID. NO. 5), precursor polypeptide (SEQ. ID. NO. 6), and mature polypeptide (SEQ. ID. NO. 7) (see specification, page 11, line 22-page 13, line 20). Similarly, SEQ. ID. NO. 15 is a Beta-defensin inducing agent polypeptide sequence and SEQ. ID. NOs.

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16-18 are nucleic acid sequences encoding such a polypeptide (see page 3, lines 14-21). SEQ. ID. NOs. 3, 9, 11, and 13 are polypeptide sequences for Beta-defensin inducing agents from *F. nucleatum*, specifically a FAD-I polypeptide. Likewise, SEQ. ID. NOs. 8, 10, 12 and 14 are nucleic acid sequences encoding such polypeptides (see page 3, line 29 – page 4, line 7). Finally, SEQ. ID. NOs. 19-21 are sequences of an HIV protein, which also act as BD-inducing agents (see page 16, lines 9-17). Therefore, the requirement to elect only one polypeptide sequence SEQ. ID. NO. and only one encoding nucleic acid SEQ. ID. NO. is improper. Withdrawal of this requirement is respectfully requested.

While the Applicant traverses the restriction requirement, the Applicant also recognizes the requirement to elect an invention for prosecution, and elects SEQ ID NO 1 and SEQ. ID. NO. 7.

The Office action was mailed on 5 December 2005. The Examiner set a shortened statutory period for reply of 1 month from the mailing date. Therefore, a petition for an extension of time (one-month) is hereby made with this response and the Commissioner is authorized to charge any fees to satisfy the fee due for this extension to Deposit Account 15-0450. No other fees are believed to be due.

Respectfully submitted,



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